Minsk Trip Report August 13-19th, 1995

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This report describes the activities of our trip to Minsk, Belarus during August 13th through August 19th, 1995. The purpose of this trip was to work closely with Artur Kuvshinnikov on the design and development of the data management system in support of the BELAM Chernobyl Thyroid Project. The American group was led by Dr. Herman Mitchell, an epidemiologist from the New England Research Institute (NERI) in Boston and two of his colleagues; Foss Tighe, a computer specialist with training in public health and Director of Systems Development at NERI; and Alon Bodnya, a native Russian-speaking programmer/analyst with considerable experience in the implementation of large scale epidemiologic investigations. To their credit, both Foss and Alon had read and virtually memorized the Manual of Operations for the project. When we began our meetings we were able to begin work immediately with no time lost bringing these two up to speed.

Parts 2 and 3 of the trip report were written before the group left Minsk and copies were left with Artur Kuvshinnikov and Michael Orloff. Drs. Michael Orloff and Everett Mincey sat in on a large portion of our meetings and provided considerable assistance in interpreting some of the clinical and laboratory procedural issues. They bore with us as we plowed through every step of the Manual of Operations and every question of the study forms.

We took two different approaches to ensuring that all data system issues were covered. First, we went through the Manual of Operations page-by-page, identifying and then defining the data management tasks associated with each section of the MOP. Secondly, we went through the entire data flow and patient flow to assure that each step of the process had a clearly defined task specification and that it was documented properly in the MOP. As a result of these approaches we were able to identify areas a few areas of the protocol which were inconsistent with the needs of the data management system or not defined well enough to unambiguously operationalize. Part I of this trip report focuses on the study forms and manual of operations, especially with regard to potential problems with the data management system. Part 2 of the trip report is a detailed accounting of all the tasks required for the study data management system. This task list includes detailed specifications regarding each programming task, the system design implications, linkages to other parts of the data and study management system and even details as to when the programs and study management reports should be run. Part 3 of this trip is a Russian overview of the data system recommendations and is a companion to the Part 2 task list. We also worked with Artur on a overall data and patient flow diagram which schematically presents all the steps of the project. Artur was putting this diagram onto the computer system in Minsk when we left and we expect to receive a copy this week.

Finally, a fourth part of this report is an addendum describing a meeting that was held for the Belarussians with Dr. Stozharov regarding the BELAM project.

It should be noted that programming for the BELAM project will soon begin in earnest and all project personnel (American and Belarussian) should realize that changes to the MOP may well have dramatic impact on the programming work, database design and the overall logic of the data flow. Suggested MOP changes should be reviewed by Artur Kuvshinnikov to gauge the impact of these changes on the data system design and/or work already completed.

This meeting seemed to this author to be a very productive meeting regarding the data system and study procedures. While I had anticipated that having a Russian speaking programmer along would facilitate the process, I had no idea how very helpful it would be. In prior meetings, held during previous trips, a great deal of time was lost trying to translate complex technical concepts through the Radiation Institute interpreters. Concepts like 'setting field flags' and 'quality control edits and verification reports' were long and drawn out, confusing conversations. Mr. Bodnya who developed his programming and system design skills in Russian was extraordinarily adept at explaining and translating the most complex technical design and programming issues. This meeting moved faster and accomplished more than I had ever hoped. Artur paid our group the best compliment when he summed up at the end of the week by saying that he appreciated the opportunity to work with this group 'who knew his job even better than he did.'

Having a strong working group in Minsk (with Foss and Alon) reinforced and clarified one more issue for me, that being that Artur is a very knowledgeable and capable person to setup and run the Data Coordinating Center activities. He knows the detail of every aspect of the study very well - probably better than anyone in Minsk and he thoroughly understands the most complex issues regarding the study implementation and data collection procedures. Again, having Alon Bodnya and Foss Tighe along allowed us to work at a very high level of sophistication and Artur never missed a beat.

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Part 1. Considerations for Forms and Manual Of Operations

This part of the of the Minsk trip report focuses on those issues that were raised during the design of the data management system which have implications for forms design and the details of the manual of operations

1. Raion Appointment Reminder Lists

Artur has suggested that communications between the Raions and DCC would be much improved if Modems were made available to the Raions. The Raions currently have computer systems and a relatively inexpensive 9600 Baud modem at each Raion would be permit rapid updates to reminder lists and address changes. Approximately 12-15 modems would be needed to supply all the Raions.

2. Subject ID Labels

It was suggested by the data management working group that study forms should reside at the various examining stations rather than being pre-labeled and placed in an envelope. The subjects envelope with contain all labels for study forms (but not specimen labels) and the study Control Form. At each examining station, the study personnel will remove a label from the subject's envelope, label and complete the study form and return this form the to subject's envelope. The last paragraph of Section 5.1 of the MOP should be changed to reflect this modification.

3. Preliminary Summary of Medical Findings and Recommendations Form

This form competed by the endocrinologist at the end of the study visit should indicate whether the subject is being referred to the clinic (Aksakovchina) for a fine needle biopsy or for some other reason. If this form indicates that the fine needle biopsy is to be performed then an edit against the Hospitalization Form can be performed to insure that the procedure was in fact completed and a diagnosis returned. Apparently there a number of reasons in addition to the fine needle biopsy that the child could be referred to the clinic.

4. Locator Form

As indicated by paragraph 2, Section 5.1, the Locator Form will be employed to capture information regarding the child's home polyclinic. This information will be used to send the above Preliminary Summary Form to the polyclinic. This form does not contain a space requesting the home polyclinic name and address. It should be modified to collect this information.

The locator form will have the current name and address information as verified by the registrar. Except for the Summary of Medical Findings which will be sent to the polyclinic, it seems unnecessary to repeat this information on other forms - it will only get into the database from the locator form.

5. Hospitalization Form

This form should indicate that a biopsy was performed. Dr. Orloff stated that children could be referred to the hospital for reasons other than a biopsy.

If the results from the fine needle biopsy are ambiguous, a second biopsy will be performed, but only one (the final) Hospitalization Form will be entered. Each week the DCC will prepare an alphabetized list of subjects of all patients referred to the clinic, so that the clinic registrar will know who to expect for a study visit.

Michael Orloff suggested that the Hospitalization Form should include the signature of the person making the diagnosis and it should also contain a space for the chief endocrinologist sign off on the form.

When a referral to the clinic at Aksakovchina is made, the dispensary Registrar will prepare an envelope for the subject which includes a referral card (with official stamp), a Hospitalization Form with subject ID applied, and two additional subject ID labels. If the appointment at the clinic is within the next week the Registrar will give the envelope to the family to take to the clinic. If the appointment is further away than a week, the Registrar will give the family the referral card and send the envelope to the clinic Registrar.

6. Adverse Events Form

It was suggested that adverse events be spread across the appropriate study forms rather than being a separate form. In other words the Blood Specimen Collection form would have space for adverse events related to that procedure, similarly with the ultrasonography, etc.

7. Initial Abstract Form

Section 3.4 of the MOP states that this form will be employed to gather addresses subsequent to 26 April 1986. However, the form does not provide space for the collection of this information. Also in this Section (3.4) of the MOP (top of page 3-5) the second to last paragraph of the section indicates that "Organizational responsibility for this work will be assumed by the data coordinating Center." Artur would like to have that read "...be assumed by the Epidemiology Group and the data coordinating center."

The Initial Abstract Form should include a question to indicate the disposition of the initial search, e.g., suggestions from the working group include:

"Address found and letter sent"
"Person located, but has left the country"
"Person not found, after ___months"

8. Thyroid Examination Form

This same form is completed by both the endocrinologist and the ultrasonographer; therefore, it should indicate which person filled out the form. This will permit differences to be examined and completeness of data collection to be verified.

9. Laboratory Procedures (Forms and Labels for Specimens)

Forms for urine collection and blood draw will be kept at the collection site. Also, a set of labels for the specimens will be with these forms. The lab tech will take the next available row of foil-back specimen labels and put one on the collection form along side the subject ID label. This procedure will establish the link between the subject's ID and the specimen ID. The remaining specimen ID labels will be attached first to the larger urine collection tube, then to the aliquotted specimen tubes. The same procedure will be followed for the blood draw. Namely, the phlebotomist will put the subject's ID label on the blood collection form and along side it will be placed the unique specimen ID label. The remaining foil-back blood specimen labels will be placed on the aliquotted tubes.

10. Urine Collection

It is stated in Section 6.1 of the MOP that 80-100 urine specimens will be collected per Raion. In order for the data management system to select the appropriate number and timing for urine collection subjects a procedure must be defined. Since this selection is based upon current Raion, not the Raion of initial exposure from the dosimetry database, it is not clear exactly how to randomly select the subject for the urine specimens. It was made clear to the working group that the Raions will vary widely in terms of the numbers of subject that they contribute to the study. In fact some may contribute only 80 or 100

subjects. It is possible to 'front load' the selection of subjects for urine specimens which will ease this problem but a scheme needs to be defined so that the data system can indicate which subjects are to have urine specimens collected.

In the laboratory, the lab tech will scan one tube into the laboratory computer to establish the work-load list. The software for printing these lists will be purchased by Dr. Mincey.

There seems to be some confusion as to what 'date of processing' means on the urine collection form.

11. Blood Collection

The lab tech will scan the one tube that will be placed into long term refrigeration to establish the work load list. The other two tubes will be used for immediate analysis. The results of the analyses by work load list (for both urine and bloods) will be transferred as a group via diskette to the dispensary computer system. The dispensary computer system will link subject IDs with the specimen IDs and will print all lab results for the endocrinologist's Final Summary of Medical Findings and Recommendations Form.

12. Control Form

This form should permit a not applicable 'n/a' response to the Urine Collection question, rather than just yes and no. The registrar should check the n/a box when the subject is not selected for urine collection.

13. Final Summary of Medical Findings and Recommendations Form

Dr. Mincey suggests that section 3 be swapped with section 4. In other words the medicine recommendations should come before the 'Recommendations' section'. Dr. Mincey also questioned why the endocrinologist would be making the diagnosis of 'Nonneoplastic vs. neoplastic' nodes without the pathology report - shouldn't this be made after the path report is returned. Section 7 of the MOP states that this form is completed before any biopsy or pathology results are available.

Section III of this form should indicate if a referral to Aksakovchina has already been made or if a new referral is needed.

A suggestion was made (after discussion by Michael Orloff, Artur Kuvshinnikov and Everett Mincey) that maybe we could include more data on the Final Summary of Medical Findings and Recommendations Form so that it would be more helpful to the polyclinic.

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Part 2. Programming Tasks Outline:

(This report was prepared in Minsk and left with Artur Kuvshinnikov. It is expected that it will form the basis for the Data Management Manual of Operations.)

During the period of August 14th to 18th, 1995 meetings were held at the Belarus Institute of Radiation Medicine, in the offices of the BELAM Data Coordinating Center (DCC) to review, discuss, and develop the data management system for the project. Attending this meeting from the Institute of Radiation Medicine were Mr. Arthur Kuvshinnov and Miss Nadya Lesnikova; from the United States, Dr. Herman Mitchell, Mr. Foss Tighe and Mr. Alon Bodnya. During the course of the week the authors of this report had the advantage of input and consultation from Dr. Michael Orlov, and Dr. Everett Mincey both of whom were present during the vast majority of the meetings. Their expert assistance in providing background rationale for a number of complicated laboratory and protocol issues was much appreciated and immensely helpful.

As a result of this meeting several documents have been produced, the purpose of this particular document is to describe the major programming tasks of the BELAM Project. Each task has a title, brief description and an indication of the frequency that the program is to be utilized during the study. Certainly, there are many ways to design a data management system for a study of this size and complexity, and the authors of this document do not mean to imply that this list of tasks and programming modules is either the only approach, nor is it necessarily exhaustive. There are a number of details missing from this list which were discussed during our meetings and were felt to be necessary, yet minor components, which did not need to be detailed in this document.

For the most part, the programming tasks which are detailed below are in the order that they are needed for the implementation of the project.

1) Create Cohort Table:

Once at start of study

This 15,000 record table will be electronically created by copying selected records from the Dosimetry data base. Records could be flagged for selection by the Dosimetry Group based on the eligibility criteria. This table should capture the original data from the

Dosimetry table, it should also include a study ID field, and fields necessary to accommodate the information within the Initial Cohort Form. Additional fields will also be needed as flags. At least two randomization fields will be created. These fields will be filled with a random value between 0-1 in .#### format when the record is originally created. One will be used for Batching of EPI tracking and appointment scheduling, while the second will be used for Urine test selection. A current clinic field will be initialized to a code that represents the Dispensary.

At this same time a VISITS table should be created that contains one record for each record in the Cohort table. This record should include an visit indicator field that should be set to a value that means "baseline". Additional fields will include appointment date, time, confirmation status, actual visit date and time, as well as various status fields for each of the study forms due at the various visits. It will also include a Visit Status field which is initialized to 0, as well as an appointment location field.

2) Assign EPI Initial Cohort Tracking Batch

As Needed by EPI group

This program will be used to break down the original 15,000 records into more manageable batches for the EPI group to investigate. As tracking skills, techniques etc are likely to change over time it is best not start with a particular exposure group, or region. The DCC and EPI group will decide on a reasonable size batch, and this program will use the EPI tracking Random number in the Cohort table to sort the table. This program will then assign the next highest EPI Initial Cohort Tracking number to the number of subjects requested to the Cohort records that have no batch number yet.

3) List Cohort by Raion

As Needed by EPI

This program will prompt for a Cohort Tracking Batch number, then produce printouts, by Raion, for each subject in the Batch. Listing will include ID, Name, Address at time of Accident, and DOB. This list will be forwarded by EPI to the Raions for obtaining address and other Initial Cohort Form data.

4) List Cohort by Last name with possible electronic matches

As Needed by EPI (Options 3 & 4 should generally be run together)

This program will prompt for a Cohort Tracking Batch number, then produce a printout by Last name, showing the ID, name, address at time of accident, DOB. It will also show any possible matches from the WHO, Dispensary or Minsk Phone Number data base, any possible matches by Last name, first name, and DOB. If only the first initial of the first name is available, all matching first initial will be included in the possible match list. These possible matches will show whatever information in these data bases that might be helpful to EPI in locating and confirming the correct identify and address of this subject.

5) Data Entry of Initial Cohort Form

This program is used on an ongoing basis

This program will be used by the EPI group (or perhaps DCC) to enter Initial Cohort forms into the system. Though ideally all fields will be completed on this form, it will be possible to enter this form when only an address has become available, the subject has died, or moved out of the country. Depending on the source of the information the EPI group may be able to complete the entire form, or may find it easier to just enter a current address and seek out the medical history and interim address information at a later time. This program will require a complete address. Once the form is entered the program will update some Cohort Table flags. If the address is entered and no death information is entered, a Cohort Table status flag will be set from 0 to 1, indicating that this subject can now be scheduled.

Based on what data is entered during this step, flags in COHORT, I_COHORT_MED and I_COHORT_ADDR should be set to indicate if the medical and address history portions of the Initial Cohort forms have been entered. (Reminder reports will need to be developed for EPI to ensure that this data is eventually collected and entered - no task is included in this outline for this purpose).

6) Assign Appointment Scheduling Batch Number:

Once per month for a month at least 2 months away

The program will ask for a month starting date, examining clinic code, and the number of subjects that can be scheduled per day. (Days may need to be broken down into 2 hour time blocks for this program). This program will scan the Visit table for

records that have a corresponding Cohort Status =1 (meaning the subject can be scheduled), Cohort current examining center matching the selected examining center. These records will then be sorted by the EPI Appointment Random number in the Cohort table. The program will also figure the highest Appointment Batch number currently on file in the Cohort table, and display the next highest number as the batch number to assign.

The program will then figure out how many screening days are available in the month indicated by the start date. (The system may need to reference a holiday table to ensure that holidays are not counted as possible screening days). If the number of patients that can be scheduled exceeds the number of schedulable cohort records a warning should be displayed. (Maybe program should allow adjustment in patients per day at this point).

The program should then proceed through the Cohort VISIT records as ordered by the random number and assign appointments dates and times to each record. (Times should be assigned in 2 hour blocks 8-10, 10-12 and 12-2. The number assigned to each block should be Visits/day divided by 3. Code will have to make sure rounding errors are handled properly.) Replace the COHORT Appointment Batch number with a Batch number calculated above. The Visit Appointment Status field should be set to 1 (indicating the record is in the scheduling phase).

Lastly a new record will be added to a BATCH table. This table will include the batch number, date batch number was assigned, screening site that it was assigned to, number of visit records that were given appointments. These fields will be filled immediately. Additional fields will include date of Ministry letter, date of scheduling letter, date of non-response list, date of no show list, and possibly counts of Baseline visits, confirmed appointments and actual visits.

NOTE: Some additional modifications would be needed to make this program work for the follow-up visits as well. The original scan would be for visit records pertaining to baseline visits or visits where the start date was less than or equal to the start of the visit window. The visit window (as defined by two date fields in VISITS), and the visit scheduling status was 0. Follow up visit records should be added to VISITS after each visit occurs. (See task 21)

7) Print Labels for Minister of Health Letter

Once per month for batch that is at least 2 months away

This program will prompt for an appointment batch number (possibly a pick list from the BATCH table). Then the program will scan the Cohort table for records that

match that Appointment Batch number. The program will then produce mailing labels or print envelopes for all records that have not had a baseline visit (either a flag in COHORT or a check into VISITS). This last rule will enable the same program to be used for follow-up visits - assuming that we don't want the ministry letter to go out prior to scheduling follow-ups. Lastly the program will fill in the Minster letter date field in the BATCH table.

8) Appointment Letters

Run one week after step 7

This program will prompt for a Appointment Scheduling Batch number (picklist from BATCH table). Then it will produce a custom letter to each of the Subjects where the current Appointment Batch number in the COHORT table matches the selected number. Custom letter might be done by creating a Word Mail Merge file or data base application can create letter itself. Letter will include name, address of subject. The text is yet to be determined, but it will explain the enclosed post care, and instructions. The letter will include three appointment dates. The subject will be encouraged to attend the first choice. This will be date and time stored in the VISITS table. A temporary table should be created that includes all the examine center dates during the target month (again excluding any holidays). Then it should be sorted by date. For each subject their primary appointment date should be located in this table. The first alternative date should be seven dates after their primary date. If the end of the file is reached, counting should resume at the first date in the month. The second alternative date should be seven dates prior to the primary date. Again if the beginning of the table is reached, counting should resume at the end of the table. Lastly, the times of both alternative dates should be fixed as 8:00 AM. These dates do not have to be stored because they can be mechanically figured based on the primary date. This will also ensure three evenly distributed dates within the month, and second and third alternatives will be evenly distributed on all days.

Lastly the program will fill in the Appointment Scheduling date field in the BATCH table.

9) Appointment Return Post Cards:

Run at the same time as task 8

This option is almost identical to the step 8. However the product is a post card. No update of the BATCH table is needed.

10) Appointment Entry/Cohort Update

Ongoing as needed by EPI and DCC

This data entry routine should prompt for an ID (bar code scanning). Then the screen should display the primary appointment date and time from VISITS table (once past baseline, this program will have to scan VISITS for the record with the scheduling status of 1 or 2. If an alternative appointment was indicated on the card, or by call in to EPI, that date should be entered over the default primary date and time. Lastly, the screen should display a data entry screen for any Cohort information that might be received on the Appointment post card, including spelling of name, address, and phone number. After user confirmation the VISITS status flag will be set to 2 to indicate a confirmed appointment.

11) Appointment Reminder Letters

Weekly (Wednesdays) for appointments the following week.

This program will produce reminded letters for appointments coming up next week. This program will prompt for a examining location and a date range (it should default to the following Monday thru the following Friday). The program will scan VISITS for the confirmed appointments in the desired date range and at the desired examining center. This program will either print letters directly or produce a mail merge file for use in Word for Windows.

12) Raion Appointment Reminder Lists:

Weekly like task 11

This program is similar to task 11, but it produces a list by Raion of subjects with appointments. It will include ID, Name, address, phone and date and time of appointment. It will be given to EPI, who will forward it to Raion by appropriate method.

13) Registration Log:

Once per week, one week prior to target week

The program will prompt for a date range, sort order and examining site. This program will allow registration logs to be printed in several forms. The sort order will be last name or by appointment. Both orders will include both confirmed and non-confirmed appointments. In the name ordered option non-confirmed appointments will be marked

with an astrict in the appointment order, the non-confirmed should be at the end of the day. The log should show the ID, name, address, date and time of appointment, and if appropriate a flag to indicate that the urine should be collected on the subject.

Urine collection status is determined by checking the RAION table for the subjects Raion. If the value stored in Urine Percent field is < or equal to the subjects Urine Randomization field in the Cohort table and this is the baseline visit, the VISITS urine status form is set to a code that indicates the form is expected, and the flag is printed on the registration form.

14) Subject ID labels:

Once per week, one week prior to target week

This program prompts for a date range, and examining site. This program will print bar coded labels for subjects who have confirmed or non-confirmed appointments in the desired range and the COHORT current examining site equals the selected examining site.

A fixed number of bar code labels will be printed for each ID. To allow all forms, Control form, envelope, and possible referral forms (4) to have a label. The label will include the ID, name, and visit indicator (#) as well as a bar code of the subject ID.

15) Specimen Labels:

Additional labels printed as needed.

This program will print generic specimen labels. The highest specimen label number should be stored in a data base so each time this program is run, it knows to start at the next highest number. Bar coded specimen labels will be printed on foil back labels The Label will be in a YYXXXXX format, where YY is the last two digits of the year, and XXXXX is a sequential number. The program should prompt for a number of IDs desired.

For each id, one row of 6 identical labels will be printed. After each row the sequential number XXXXX should be stored back to a data base, so if printing fails, restarting the program will begin with the next number.

Because of the year portion of the label format, the counter stored in the database will have to be reset on the first of each year prior to printing any specimen labels. These labels will be given to the specimen collectors at the examining sites to use as needed.

16) Clinical Unit Referral Lists:

Run Weekly

This program will produce an alphabetical list, by last name, of all subjects that have been referred for follow up at the clinical unit. The program will scan for Preliminary Results and Final results forms where a referral was indicated and no hospitalization form is on file yet. This list will include ID, name, date of screening exam, address and phone if available. It will be sent to the clinical unit.

If at a later date, additional hospitals are certified as providing study referrals, the Findings forms will have to be altered accordingly, and this program will have to prompt for a specific Clinic Unit or Hospital.

17) Non-Response List:

Run Monthly - Mid month for batch corresponding to appointments during the previous month.

This list will provide a list of all subjects who were sent an appointment letter, but never responded. The program will prompt for a Appointment Scheduling Batch number (from a pick list based on BATCH table). The program will scan cohort table for matching Appointment Scheduling batch number, and if any VISITS record has a VISIT status flag of 1, then it should be included in the report. The report should include ID, name, address, phone, visit for which subject was non-responsive, and batch indicator. It should be optionally sorted by Last Name or Raion.

Once complete the program should prompt user for confirmation that the print run worked OK. If so, the program should set all the VISIT statuses to 11 (indicating non-response), and the BATCH table Non-Response List date should be set to the current date.

List is delivered to EPI for Follow up.

18) No Show Report:

Run Monthly - Mid month for batch corresponding to appointments during the previous month.

This report will prompt for a Appointment Scheduling batch number (picklist from BATCH table). It will scan VISITS for records with the Visit Status field equal to 2, and a corresponding COHORT appointment scheduling batch number matching the desired number. This list will be sorted by last name or Raion. It will include ID, name, address, phone if available, appointment date missed.

Once complete the program should prompt the user for confirmation that the print run worked OK. If so the program should set all the VISIT statuses to 12 (indicating No show). and the BATCH table No Show List date should be set to the current date.

The list is then delivered to EPI for investigation.

19) EPI Follow-up Data Entry:

Used by EPI and DCC as needed.

This program will prompt for an ID number. Then is will display the current status of the subject (checking both COHORT status and VISITS. visit status fields.) The operator will have the option of entering a new address for the subject and/or changing the status. The options include: Setting subject back to schedulable. COHORT Status=1, and most current visit record status to 0. Or indicating subject moved out of country (set COHORT STATUS to 13 and visit status to 13. Or indicating the subject has refused, set COHORT status to 14 and VISIT status to 14, Or indicating subject has died, set COHORT and VISIT status to 15.

Lastly, no matter what the change the system should prompt for a comment that gets stored in a comment table associated with the ID.

If a subject is set to schedulable, the COHORT Cycles field should be incremented by 1. To indicate that one scheduling cycle has been completed without success but another will soon be attempted. The cycles field should be displayed on the DE screen described above as information only.

20) Data Entry of Control Form:

As soon as possible after screening

This form will be like other data entry routines, however it will play an important role. Control forms should be entered as quickly as possible after a visit. Entry of a control form will be used to determine if a subject is no-show. Once a control form is entered, it will update the VISIT table status field to 3 (visit conducted). Entry of this form should also fill in the actual visit date and in time in the VISITS table.

21) Data Entry of Summary & Final Results:

As soon as possible after form completion

These forms will be like other data entry routines, however it will be play several important roles. Entry of this form will have a couple special functions. If this form indicates that there was a referral to the Clinical Unit, the VISIT status flag for the Hospitalization forms will be set to a status indicating that the form is expected. Entry of this form will also mean that the subject will appear in the weekly Clinical Unit lists (Task # 16). Lastly the Final form has a very important task it should create the next record in the VISITS table for this subject. If the recommendation was for a six month Follow up, a new record should be added to visits with the next highest number, and having a window that is 6 months form the current visit (plus or minus one month). Otherwise a new record should be added with a window 12 months from the current visit date (plus or minus one month).

22) Merge Central Lab Data:

Done weekly or as new data becomes available from central lab

This program will read a diskette from the central lab into the Examining center computer. The specimen IDs will be cross referenced with blood and urine collection forms to figure the subject ID for each test result. Records will be added to the laboratory results tables. Results will not be accepted for visits that do not have a VISIT status of 3. (Controlled by data entry of Control form).

23) Print Central Lab Results for Endocrinology Review

Run after task 22.

This program will scan the central lab data for new complete records. If all lab results are in (or have missing values), VISIT urine collection form status will be checked

to determine if the urine results are expected for this subject. Then output should be produced. It will include a list of all IDS, names, with all lab values for review by the Endocrinologist.

Output is given to Endocrinologist for review and production of Final Summary of Medical Findings and Recommendations form.

24) Print Central Lab Results for Individual File

Run after task 22.

This program will scan the central lab data for new complete records. If all lab results are in (or have missing values), VISIT urine collection form status will be checked to determine if the urine results are expected for this subject. Then output should be produced. It will include ID, name, and all lab values for a particular study patient.

Output is placed in individual patient file and possibly sent to the Polyclinic along with final results summary.

25) Final Results Summary Referrals:

Run Monthly.

This program will scan the final results summary forms for subjects that had referrals to the clinical unit on the Final report, but did not have a referral on the Preliminary report.

This list will be brought to the attention of EPI and Clinical staff to ensure that appointments are made for the necessary Follow up.

26) Data Entry of Other Forms:

As soon as possible after form completed

All study forms will need data entry routines. Some will require special update steps. For instance the Hospital Form data entry will check the question on fine needle biopsy, if this is Yes, then it will change the status flag in Visits to the Fine Needle

biopsy and Anatomical Pathology form status flag in Visits to a status that indicates that the form is now expected.

In addition all data entry routines should update a status field in VISITS to indicate that the particular form has been entered (It might be nice to distinguish between entered with pending edits, and entered and all data complete.)

27) Reports:

As needed

There are wide range of reports that might be useful in this system:

Visits Conducted in a given time period
Visits Conducted in relation to their Visit Windows
Visits with no-show or non-response status (by Raion?)
Subjects Dead, Refused
Total Urine Results by Raion
Forms by status (Expected, complete, Missing) by visit, time frame, etc.
Batch summaries showing no show rates, non-response rates
Cohort Records Schedulable

Sample Table Structures:

The outline below does not represent the complete number of tables, or fields within tables. Its main goal is to provide some description of the fields that would be needed to operationalize the programming tasks listed above. Table names and fields names listed here are just suggestions and should be altered to make them meaningful to the Belam programming and data management team.

COHORT Table:

One record for each of the 15,000 subject selected from the Dosimetry data base. Created all at one time.

ID	Character	7	
FNAME			Subject First Name
LNANE			Subject Last Name

MNAME			Middle Name
ADDRESS			(Fields to hold address at time of accident)
CURR_ADDRESS			(Fields to hold current address) * Updated by Initial cohort form, locator forms and Tasks 10 & 19)
RAION			Raion at time of accident
STATUS	Numeric	2	Status Flag 0=Pending EPI Search/Entry of Init. Cohort Form 1=Address found ready for scheduling 13=Moved out of country 14=Refused 14=Died
URINE_RAND	N	3	Random number 0-1 initialized at time of creation of cohort record. Used for picking whether to do a Urine Test
EPI_APPT_RAND	N	3	Random number 0-1 initialized at time of creation of cohort record.Used for batching names to EPI for Initial cohort form, and for creating Batches of subjects for scheduling.
BL_COMP	N	1	Flag indicating if the subject has attended the the baseline visit.
I_COHORT_MED	N	1	Flag indicating if the Initial Cohort medical data has been competed
I_COHORT_ADD	N	1	Flag indicating if the Address history information portion of the Initial Cohort Forms has been Completed.

Other fields to accommodate initial Cohort form date (except address history and death)

VISITS Table

One record for each Subject Visit (adding only one visit at a time). Baseline Visit is created when COHORT table created. After entry of Final Results form, follow-up visit record is added to table with appropriate visit window.

ID			
VISIT	N	2	0=Baseline, 1 = 1st Followup, 2 = 2nd Followup etc
START_WIN	Date		Start of study visit window (Blank or baseline)
END_WIN	Date		End of study visit window (blank for baseline)
VISIT_DATE	Date		Date of actual study visit
VISIT_TIME	C	7	Time of actual study visit
APPT_DATE	D		Primary/Actual Appointment date

APPT_TIME	C	7	Time of Primary/Actual Appointment time
STATUS	N	2	0 = Not in scheduling phase yet 1 = Batch in Scheduling Phase (letters being sent) 2 = Appointment Confirmed 3 = Visit Occurred 11= Non-Response 12= No show 13 = Moved to another country 14 = Refused 15 = Died
LOC_STAT	C	1	Status of locator form ? = Expected not entered yet P = Entered, edits still pending C = Complete all edits resolved M = Missing N = NA
INT_STAT	C	1	Status of Interview form ? = Expected not entered yet P = Entered, edits still pending C = Complete all edits resolved M = Missing N = NA
URI_STAT	C	1	Status of Urine Collection form ? = Expected not entered yet P = Entered, edits still pending C = Complete all edits resolved M = Missing N = NA
BLD_STAT	C	1	Status of blood collection form ? = Expected not entered yet P = Entered, edits still pending C = Complete all edits resolved M = Missing N = NA
CNT_STAT			Status of central lab data

etc for each form possible due at a visit. Initial values for these fields should be set when the data entry person first enters any visit data (usually the first form is the control form). At this time the status of each form should be set to ? (expected) or N (NA). Some fields will have their status changed form NA to ? based on the data entry of other forms.

BATCH Table

One record for each Appointment Scheduling Batch.

BATCH	N		Batch Number
EXAM_SITE	N		Code for examination site
BATCH_DATE	Date		Date Batch Number assigned
BATCH_COUNT	N	3	Number of subjects in Batch
MIN_DATE	Date		Date labels generated for Health Minister Letter
APPT_DATE	Date		Date Appointment Letters generated
NONR_DATE	Date		Date Non-respondent list generated
NOS_DATE	Date		Date No -show list generated
BASE_COUNT	N	3	Number of baseline Visits in Batch
CONF_COUNT	N	3	Number of subject confirming a baseline visit date
VISIT_COUNT	N	3	Number of subjects attending visit

RAION Table:

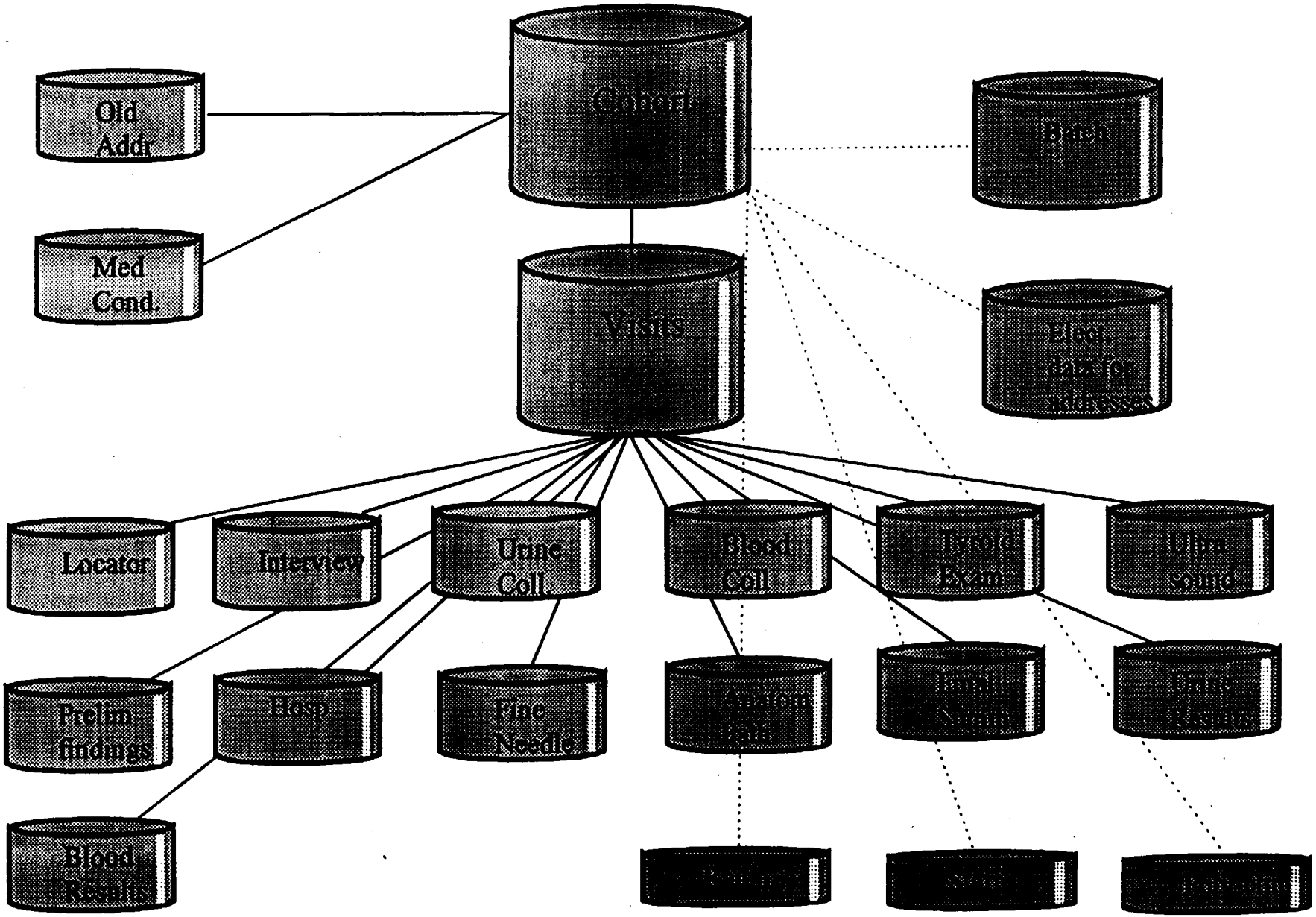
RAION	??		Raion ID Code
URI_PERCENT	N	3	Percent of subjects form this Raion that need to be selected in order to get 100 subjects from that Raion once ½ the subjects have had the baseline visit.. This is calculated at study start, adjusted periodically. A proposed method would be to use the initial 15,000 records and count how many where located in each Raion at the time of the accident. If a Raion had 1000 subjects at the time of the accident then the percentage would be 100/(1000/2) = .20. that would result in 20% of the subjects form that Raion being selected for urine collection. The totals tested would have to be carefully monitored such that when it reached 100, the percentage would then be set to 0 so that no additional subjects would be selected from that Raion. Manual adjustments to this fields field might be necessary to Raions where there has been substantial emigration since the accident, to ensure that the desired number is reached. Creation of this table should probably be done as part of task 1.

HOLIDAY Table:

One record for each holiday each year where the Examination Site is closed.

HOLIDAY	Date	Date of a examining centers holidays

BELAM Database Structure



Minsk Trip Report
August 13-19, 1995

Herman E. Mitchell, Ph.D., Foss Tighe, Alon Bodnya

Part 3: Russian Overview of Data Management System Recommendations - Alon Bodnya

Результаты и выводы визита рабочей группы программистов/аналитиков

США по проэкту БЕЛАМ.

1. Согласованы состав и расположение компьютерного оборудования. Рассмотрены вопросы о конфигурации дозиметрического компьютера и прокладке линии связи между диспансером и ЦКД. Принято решение о вводе данных с форм заполненных в клинике в ЦКД. Эпидемиологическая группа ответственна за ввод данных с Формы Исходной информации. Центральная лаборатория пересылает данные (на дискетах) в диспансерный компьютер для последующей пересылки в ЦКД.

2. Предложено внести изменения в протокол исследования (Существенные в главы 3 и 4), касающиеся выбора 15000 потенциальных кандидатов обследования (вместе с дозиметрической группой), метода рассылки писем и карточки регистрации. Определены функции Эпидемиологической группы по обнаружению адреса проживания детей. Принято решение о методе сбора паспортной информации пациента, ее регистрации и учета в АСУ (решено что будут использованы несколько Баз Данных Первичной Информации, такие как БД Гаврилина, БД WHO, БД диспансера, БД МВД итд.). Таже определены значение и пути циркуляции Формы Исходной информации между Эпидемиологической группой и ЦКД, согласования даты визита и высылки приглашения на обследование. ЦКД также несет ответственость по печатанию отчетов о ненайденных пациентах, пациентах не приславших карточку регистрации в ЦКД, умерших или отказавшихся от участия в исследовании пациентов. Отбор пациентов для визита на следующий месяц будет происходить в пакетном режиме.

   Разработаны алгоритмы по случайному выбору 3-х возможных дат визита пациента в диспансер и назначению анализа мочи узкой группе обследуемых. Проделан дезайн Регистрационного Журнала и 3-х сопровождающих его отчетов. Решено привлечь районные поликлиники в поиск адреса пациентов и напоминания им о дне назначенного визита (ЦДК ответственен за печать 2-х соотвествующих отчетов).

3. Этикетки (Labels) будут печататься в ЦКД. Идентификационный Номер (ИН) будет назначен при выборе исходной группы пациентов (15000) и включен в Регистрационную карточку и Форму Исходной информации. Одна этикетка также будет печататься в Регистрационном Журнале. Пакет

   ИН-этикеток (20 штук для пациента) высылается в диспансер за неделю до назначенного (или предпологаемого) дня визита.

Регистрационная медсестра использует 2 этикетки для отметки в Регистрационном Журнале и обозначении конверта. Этикетки, Контрольная Форма и Locator-Форма являются первоначальным содержимым пакета. (Что требует внесения изменений в протокол - глава 5).

ЦКД также печатает лабораторные этикетки (по 6 одинаковых) для станций забора крови и мочи.

Пять этикеток используются при заборе крови (1 для формы, 1 для вакутейнера, 3 для пробирок) и четыре этикетки (с другим номером) - для забора мочи.

4. Существенно расширены обязанности медсестры регистратуры по подготовке пакета форм, идентификации пациента, и подготовке напрпавления в клинику по необходимости. Он(а) также заполняет Locator форму и делает отметку о необходимости анализа мочи в Контрольной (Control) Форме. Однако предварительное согласие субъекта на исследование будет даваться при опросе (интервью).
5. Определена последовательность прохождения пациентом станций. По мере прохождения станций пациент собирает заполненные специалистами формы (с ИН). Каждая станция делает отметку в Контрольной форме. УЗИст проводист пальпарное обследование и вслед за ним УЗИ-тест. Последним в цепочке является эндокринолог который:

   - проводист пальпарное обследование
   - сравнивает результаты 2-х пальпаций и УЗИ
   - заполняет 2 формы Предварительного Медицинского Заключения (для пациента и исследования)

6. Предварительное Медицинское Заключение является основным документом на основании которого регистрационная медсестра делает вывод о необходимости госпитализации пациента. Медсесестра выписывает направление в клинику и помечает его ИН-наклейкой а также спецальной печатью. Пациент информируется о дне госпитализации (ЦКД не отслеживает данную информацию) и получает направление на руки. Медсестра также готовит отдельный пакет (на который наклеена этикетка-ИН пациента) для клиники в который входит Госпитализационная форма (с наклеенной этикеткой-ИН), незаполненные формы биопсии и патологии, 2 этикетки. Пакет выдается пациенту на руки только в случае немедленной (в течении 0-3 дней) госпитализации. Иначе пакет высылается с нарочным в клинику.

Медсестра также делает фотокопию(и) Предварительного Медицинского Заключения и посылает ее (одну?) в районную поликлинику.

7. Оператор ЭВМ вводит все заполненные формы в диспансерную станцию (в течении 1- 2 дней) Контрольная форма вводится в день визита. Данные передаются по сети (X - 25) в ЦКД. Формы также передаются в ЦКД. На основании Предварительного Медицинского Заключения ЦКД определяет период последующего обследования.

8. ЦКД ответсвенен за печать еженедельного отчета о лицах направленных в клинику. Отчет не включает пациентов уже прошедших госпитализацию. Отчет отсылается в клинику.

9. Клиника определяет необходимость биопсии и патологискего анализов что фиксируется в Госпитализационной Форме. После выписки пациента формы отсылаются в ЦКД для ввода в ЭВМ.

10. Обработка данных в центральной лаборатории.

Пробирки с анализами получаются лабораторией и регистрируются. Transmittal (Shipment) Log Форма может быть использована для отслеживания получения отправленных пробирок. В течении недели лаборатория делает анализ крови и в течении месяца - мочи. Результаты анализов вводятся в компьютер центральной лаборатории (используя спуц. программное обеспечение). Раз в неделю данные посылаются (по дискетам) в диспансер и ИН связывается с результатами анализов через формы забора мочи и крови. Диспансерная станция печатает 2 отчета:

А) Журнал о завершении анализов (ИН, Имя и результаты ВСЕХ анализов). Отчет отсылается эндокринологу.

Б) Индивидуальный отчет результатов анализов (для поликлиники).

11. Эндокринолог заполняет форму Окончательного Медицинского Заключения. Форма вводится в диспансерный компютер. Копия отсылается в поликлинику.

ЦКД шлет открытку пациенту если госпитализация необходима. Диспансер приготавливает пакет (см. пункт 6). На основании Окончательного Медицинского Заключения ЦКД определяет период последующего обследования.

12. Рекомендуется ввести изменения в ряд форм для внедрения вышеизложенного плана (Locator Форма - адрес поликлиники, Контрольная

Форма - Вопрос о необходисти анализа мочи, Госпитализационная форма - Вопрос о биопсии итд.)

13. Список задач и их спецификация а также предложения по структуре баз данных (на английском языке) прилагаются.

Part 4. Addendum to Minsk Trip Report August 13-19th, 1995

Herman E. Mitchell, Ph.D.
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On Wednesday, August 16th, Dr. Stozharov held a meeting for all the main Belarus players in the BELAM project. (Incidently, BELAM is the title of the project that Artur Kuvshinnikov used for our Chernobyl - Thyroid Cancer project in Belarus, I assume this is was agreed upon?) This meeting was held at 12 noon and lasted approximately two hours. Artur provided a detailed report of that meeting to Everett Mincey and I. I gathered that the meeting was held in order to communicate Stozharov's position with regard to our project. My notes from Artur's recounting are as follows;

All the project leaders were present, Dr. Voronetsky was asked to present the status of his work on the project first. He stated he has been working with the Ministry of Internal Affairs to get a list of all people who were relocated immediately after the accident. This list will provide a database of the first address to which people were located, but does not include information about subsequent moves. He stated that the list will cost money. He also stated that the Institute of Sociology has received the interview forms and they will provide assistance and feedback regarding this form by the end of September.

Dr. Minenko from dosimetry spoke next. He stated that the 5,800 reconstructed doses of the Brest database are finished. The Moscow dosimetry group performed the same reconstruction. The local (Minsk) group had higher doses than the Moscow dosimetrists. The Minsk group employed an ecological model while the Moscow group took another approach. These discrepancies are to be discussed during a September meeting of the American, Minsk and Moscow dosimetry groups. Artur and Minenko then discussed the Oak Ridge compatible machine that Arthur and I had discussed with Computerland the day before. Further discussions of this configuration are to take place the week following this meeting. [Ed Note: - Computerland appears to be able to provide everything they need for that system.]

Artur Kuvshinnikov reported to the group next. He stated that the leased telephone connection (called an 'X.25 line') between the Data Coordinating Center (DCC) at the Institute of Radiation Medicine and the Dispensary will be delayed until needed. [Ed note:- This was an agreement that Artur and I came to after exploring the complications of the $5,000+ installation charge, and the $80-$90 monthly rental fee, which has not been worked out. Right now there is no one at the dispensary to use this line, and it should not be installed until it is needed. The line is not critical to the startup of the project and could be delayed until the data volume picks up.] Artur also told the group that the he has a workstation in the DCC that is ready for the Minsk Dosimetry group and can be installed in their offices as soon as they are ready for it. [Ed note: - this is a standard PC workstation which is already in Minsk and in addition to the larger system currently being configured for dosimetry Monte Carlo simulation mentioned above.] Artur also stated that the

LAN (local area network) is up and running at the DCC.

Dr. Rzheutsky spoke next regarding the state of the Dispensary activities. He reported that the study office at the Dispensary is ready. The refrigerators are installed. Yet, they have no money to hire people to begin the project. No money for the study registrar, new physicians, clerical personnel, etc. Without money to invite people to join the project at the Dispensary nothing can begin.

Artur then stated that Dr. Danileva will be the chief of the clinical component of the project. She was given the Manual of Operations and drafts of the forms.

Dr. Stozharov spoke next. He stated that money was a very difficult issue. The Institute has no money for the project and he has no idea how people can be supported to work on this project this next year. Some people who are currently working on the project are getting money from other sources (such as Artur and his programmer, Nadya). Next year they will not be able to do this. The Institute must have money for this specific project. He stated that he has money for Artur and Nadya on another project next year and that they will have to be moved to that project if money is not forthcoming. He stated that the project will be stopped at the end of this year unless money is found to support the study personnel. Dr. Stozharov then produced a timeline for the BELAM project based upon Dr. Beebe's work two months ago.

Dr. Stozharov stated that he wanted all forms ready and translated into Russian by September 1st, 1995. (Just two weeks from the date of this meeting.) Artur pointed out that no one has been assigned to do the Russian translation of these forms. Stozharov said that the person who worked on, or is responsible for, each specific form should be responsible for translating that form. Dr. Stozharov wants a pilot run-through of the study to begin in September. He wants all the data collection forms employed in the pilot and a complete run-through of the patient process (blood draws, ultrasonography, urine collection, lab work, etc.). Artur pointed out that a number of study components necessary for a thorough pilot are still in process. These components include selection of the cohort, patient lists, labels for forms, specimens, etc. Artur pointed out that study personnel have not undergone certification processes and that real patients should not be employed for this pilot. Stozharov restated that the forms have to be completed and the pilot conducted in September.

This was end of Artur's description of the meeting

[Ed note: - It was my impression that Dr. Stozharov wanted to create a flurry of activity in the project so that when he put the brakes on at the end of this year people would notice that it had stopped. At the very slow pace that some components of the project have been moving, it is not clear that anyone would notice if the project was brought to a halt.]